

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

38. (Currently amended) A method of introducing a nucleic acid encoding a foreign gene into a cell in a patient, said method comprising the steps of

(a) first administering a cell cycle blocking agent to said patient, wherein said cell cycle blocking agent is a member selected from the group consisting of cyclophosphamide, taxol, taxolene, and a vinca alkaloid; and

(b) second administering said nucleic acid to said patient within seven days of step (a), wherein said nucleic acid is administered in a lipid formulation comprising a cationic lipid and a lipid derivative selected from the group consisting of an ATTA-lipid, a polyethylene glycol (PEG)-lipid derivative, and a ganglioside G<sub>M1</sub>-modified lipid,

wherein said nucleic acid is fully encapsulated in said lipid formulation such that less than 5% of the nucleic acid is degraded after exposure of said formulation to 1 U DNase I for 30 minutes in digestion buffer at 37°C, and

further wherein transfection efficiency is increased by at least 50%.

39. (Original) The method of claim 38 wherein step (b) is performed within 3 days of step (a)

40. (Original) The method of claim 38 wherein step (b) is performed within 24 hours of step (a).

41. (Previously presented) The method of claim 38 wherein said foreign gene is a plasmid.

42. (Currently amended) The method of claim 38 wherein said foreign gene comprises a gene selected from the group consisting of genes encoding a cytokine, apoptotic protein, tumor suppressor, heat shock protein, immunogenic antigen, proteinase inhibitor, anti-

angiogenic protein, suicide gene for use in Gene Directed Enzyme Prodrug Therapy ("GDEPT")  
GDEPT, ribozyme, antisense nucleic acid, viral protein and a toxin.

43. (Previously presented) The method of claim 38 wherein said foreign gene is administered systemically.

44. (Previously presented) The method of claim 38 wherein said foreign gene is administered locally or regionally.

47. (Previously presented) The method of claim 38, wherein said cell cycle blocking agent is selected from the group consisting of cyclophosphamide, taxol, and vincristine.

48. (Previously presented) The method of claim 38 wherein said cell cycle blocking agent is in a liposome formulation.

49. (Canceled)

50. (Previously presented) A method of claim 38 wherein said cell cycle blocking agent is administered at least 32 h prior to administering said foreign gene.

51. (Previously presented) A method of claim 38 wherein said cell cycle blocking agent is administered at least 48 h prior to administering said foreign gene.

69. (Currently amended) A method of inhibiting growth of cancer cells in a patient having a cancer comprising introducing a nucleic acid encoding a foreign gene into a cell in a patient having cancer, said method comprising the steps of:

(a) first administering a cell cycle blocking agent to said patient, wherein said cell cycle blocking agent is a member selected from the group consisting of cyclophosphamide, taxol, taxolene, and a vinca alkaloid; and

(b) second administering said nucleic acid to said patient within seven days of step (a), wherein said nucleic acid is administered systemically in a lipid formulation comprising a cationic lipid and a lipid derivative selected from the group consisting of an ATTA-lipid, a polyethylene glycol (PEG)-lipid derivative, and a ganglioside GM<sub>1</sub>-modified lipid,

wherein said nucleic acid is fully encapsulated in said lipid formulation such that less than 5% of the nucleic acid is degraded after exposure of said formulation to 1 U DNase I for 30 minutes in digestion buffer at 37°C, and  
further, and wherein transfection efficiency is increased by at least 50%.

70. (Original) The method of claim 69, wherein said cancer comprises a tumor.

71. (Currently amended) The method of claim 70, wherein said cell cycle blocking agent and said foreign gene ~~are~~ is administered distal to the site of the tumor.

72. (Currently amended) The method of claim 69, wherein said cell cycle blocking agent or said foreign gene ~~are~~ is administered intravenously.

73. (Currently amended) The method of claim 69, wherein said cell cycle blocking agent or said foreign gene ~~are~~ is administered intraperitoneally.

74. (Previously presented) A method of treating a patient having a cancer comprising introducing a nucleic acid encoding a foreign gene into a cell in said patient, said method comprising the steps of:

(a) first administering a cell cycle blocking agent to said patient, wherein said cell cycle blocking agent is a member selected from the group consisting of cyclophosphamide, taxol, taxolene, and a vinca alkaloid; and

(b) second administering said nucleic acid to said patient within seven days of step (a), wherein said nucleic acid is administered in a lipid formulation comprising a cationic lipid and a lipid derivative selected from the group consisting of an ATTA-lipid, a polyethylene glycol (PEG)-lipid derivative, and a ganglioside GM1-modified lipid,

wherein said nucleic acid is fully encapsulated in said lipid formulation such that less than 5% of the nucleic acid is degraded after exposure of said formulation to 1 U DNase I for 30 minutes in digestion buffer at 37°C, and

further wherein transfection efficiency is increased by at least 50%.

75. (Original) The method of claim 74, wherein said (PEG)-lipid derivative is a PEG-ceramide.

76. (Original) The method of claim 75, wherein said PEG-ceramide is a member selected from the group of PEG-Cer-C14, PEG-Cer-C20, and PEG-Cer-C8.

77. (Previously presented) The method of claim 74, wherein said lipid derivative is present in an amount of from about 1% to about 20% by weight of the lipid formulation.

78. (Original) The method of claim 74, wherein said lipid formulation is prepared by the method comprising:

- (a) contacting said nucleic acid with a solution comprising non-cationic lipids and a detergent to form a nucleic acid-lipid mixture;
- (b) contacting said cationic lipid with the nucleic acid-lipid mixture, thereby forming a charge-neutralized mixture of nucleic acids and lipids; and
- (c) removing the detergent from the charge-neutralized mixture to provide the lipid-nucleic acid particles in which the nucleic acids are protected from degradation.

79. (Original) The method of claim 38, wherein the vinca alkaloid is a member selected from the group consisting of vinblastine, vincristine, and vinorelbine.

80-81. (Canceled)

82. (Currently amended) The method of claim ~~80~~ 38, wherein said lipid formulation is prepared by the method comprising:

- (a) contacting said nucleic acid with a solution comprising non-cationic lipids and a detergent to form a nucleic acid-lipid mixture;
- (b) contacting cationic lipids with the nucleic acid-lipid mixture, thereby forming a charge-neutralized mixture of nucleic acids and lipids; and
- (c) removing the detergent from the charge-neutralized mixture to provide the lipid-nucleic acid particles in which the nucleic acids are protected from degradation.

83. (As filed ) The method of claim 69, wherein the vinca alkaloid is a member selected from the group consisting of vinblastine, vincristine, and vinorelbine.

84. (As filed) The method of claim 74, wherein the vinca alkaloid is a member selected from the group consisting of vinblastine, vincristine, and vinorelbine.

85. (Original) The method of claim 38, wherein the foreign gene is a therapeutic gene.

86. (Original) The method of claim 69, wherein the foreign gene is a therapeutic gene.

87. (Original) The method of claim 74, wherein the foreign gene is a therapeutic gene.